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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,875	11/17/1999	DAVID E. CHARLTON	CWP-012CN3	5134
21323	7590	10/20/2003	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			DO, PENSEE T	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 10/20/2003				

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/441,875	CHARLTON ET AL.
	Examiner Pensee T. Do	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 February 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 27-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 27-55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>21</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

SUPPLEMENTAL DETAILED ACTION

1. This office action is supplemental to the previous office action sent on April 21, 2003 (paper # 20). The reason for this supplemental office action is because the US Patent Brown III (4,916,056) should have been applied instead of the European Patent Brown III (EP 217 403 A2). This supplemental office action resets the response date for Applicants.

Withdrawn Rejection

2. Rejection under 35 U.S.C. 103(a) as being unpatentable by Brown, III et al. (EP 217 403 A2) in view of Rosenstein is withdrawn herein.
3. Rejection under 35 USC 103(a) as being unpatentable by Brown III, et al. (EP 217 403 A2) in view of Ching et al. is withdrawn herein.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown , III et al. (US 4,916,056) further in view of Ching et al. (US 5,120,643).

Brown has a test device (10) comprising a casing (14) defining a sample inlet and viewing window (fluid chamber 7) and having disposed therein a test strip comprising a porous fiber matrix 12 (equates the sorbent material which defines a flow

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path for transporting the liquid sample therealong from a sample contact region to a test site and a control site (34) comprising an immobilized first protein to a ligand, and a control site (32) comprising immobilized second protein (i.e. an immobilized binder which binds to the conjugate, which conjugate binds to the ligand), and a filter means (22), which device is useful for competitive, sandwich and indirect assays. Chorionic gonadotropin is an explicitly illustrated ligand (example 3). Particles coated with first protein are immobilized within the porous fiber matrix 12 (see col. 4, line 49-col. 5, line 2). The first protein and second protein consists of a variety of monoclonal antibodies or polyclonal antibodies. (See col. 5, lines 54-56). The sorbent means 20 disposed in the casing 14 is for absorbing excess fluid during the use of the assay device. The absorbent means 20 comprises one or more layers of material and is in physical contact with the barrier material 18, when used, or with the reaction matrix 12. (See col. 10, lines 29-46).

However, Brown, III fails to teach colored particulate labels, specifically metal sols.

Ching teaches devices using chromatographically mobile specific binding reagents labeled with colloidal particles such as gold and selenium. Other methods and devices wherein labeled specific binding materials such as colloidal particle labeled and enzyme labeled materials are incorporated on the chromatographic medium of an assay device in a dry form which can be rapidly resolubilized and chromatographically transported along the medium by selected chromatographic solvent. (see col. 10, lines 37-65). The signal is visible to the naked eyes.

It would have been obvious to one of ordinary skills in the art to use the particulate labels taught by Ching in the device of Brown, III since Brown's device is applicable to colorimetric immunoassay. By using the colored labels of Ching, one of ordinary skills in the art could eliminate the step of adding a substrate to produce a visible signal.

Response to Arguments

- Applicant's arguments with respect to claims 27-39 have been considered but are moot in view of the new ground(s) of rejection.
- Regarding Applicant's argument that Brown III device is based on a well-type format where a liquid sample of interest passes through the thickness of a matrix rather than along the length of the matrix, this issue has been revisited. Please refer to paper 13 mailed on December 18, 2001 under the "response to argument" section, pages 3-4. No further discussion on this issue is necessary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641

Pensee T. Do
Patent Examiner
October 17, 2003